Notice of Grant Award (NGA)

Presented By:

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The National Institute of Allergy and Infectious Diseases (NIAID)

The National Institutes of Health (NIH)

What is a Notice of Grant Award?

- The Notice of Grant Award (NGA) is the legal document issued to notify the grantee that an award has been made.
- The NGA is issued for a budget period of 12 months and reflects future year dollar commitments.
 - A new NGA will be issued for each year of the project.

What Is a Notice of Grant Award?

- The NGA is provided in a **letter format** to facilitate the e-mailing of this award.
- One copy of the NGA is provided by e-mail or by mail to the grantee institution listed on the application.
- It is forwarded to the business person who signs the application. The business official provides the principal investigator with a complete copy of the NGA.

Notice of Grant Award

- A grantee indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office.
- If the grantee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the Grants Management Officer (GMO) immediately upon receipt of the NGA.
- If resolution cannot be reached, the GMO will void the grant.

Notice of Grant Award

- NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal.
- Once the award is accepted by the grantee, the contents of the NGA are <u>binding</u> on the grantee <u>unless and until</u> modified by a <u>Revised Notice of</u> <u>Grant Award</u> signed by the GMO.

SPECIALIZED RESEARCH CENTER

Department of Health and Human Services Mational Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Issue Date: 09/30/2004

Grant Number: 5 P50 AIOXXXXX-08

Principal Investigator: XXXXXXXXXXXXX

Project Title: Emerging XXXXXXXXX in China: Genetic Diversity,

Grant Number

DIRECTOR

CH INA

Budget Period: 07/01/2004 - 06/30/2005

Project Period: 06/15/1996 - 06/30/2007

Budget Period

Project Period

Dear Business Official:

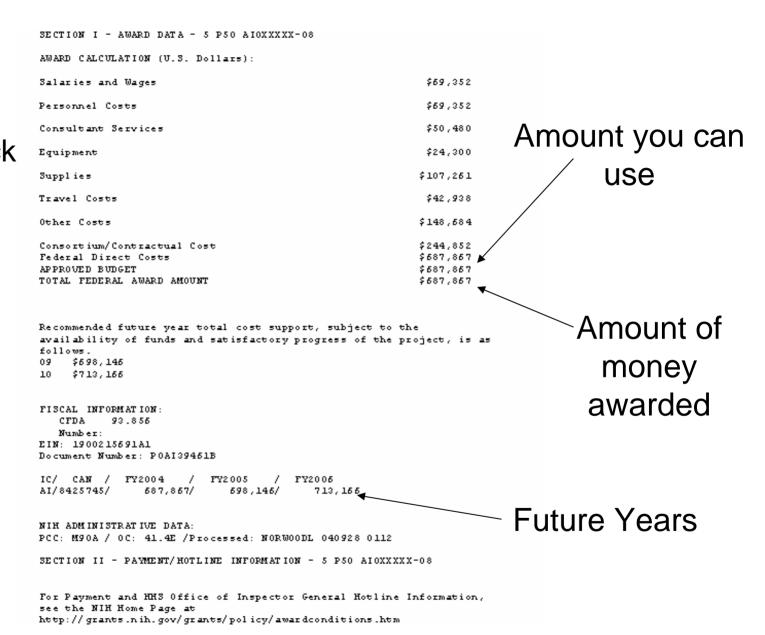
Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit http://www.iedison.gov.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Amount of Award

Always check this page to make sure you have received what you thought you should receive



Terms of Award

- Terms of Award are legally binding.
- Terms of Award accompany every NGA issued by the U.S. government.
- They can either be informational, or restrictive.
- They are often applied to clarify any funding, human subjects, or animal welfare issues.

Terms of Award

Terms of Award come from:

- Authorizing Program Legislation
- The NIH Grants Policy Statement
- Administrative Terms of Award
 Programmatic Terms of Award (written in a Cooperative Agreement RFA, and incorporated in full or by reference in the NGA)

SECTION III - TERMS AND CONDITIONS - 5 PSO ALOXXXXX-08

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at

http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Treatment of Program Income: Additional Costs

This says you must follow the NIH Grants Policy Statement.

Notice of Grant Award

Administrative Terms & Conditions of Award

- Administrative terms and conditions on the NGA may include:
 - Issues related to funding including funding restrictions
 - Human subject or animal welfare issues
 - NIAID required clinical terms
 - Special Requirement of the RFA under which the grant is awarded.
 - Special Requirement of the Institute identified Key Personnel; accrual requirements for future funding)

Administrative Terms of Award

Restrictive Terms

- There are two types of restrictive terms:
 - One which restricts the use of funds for a purpose (Example: for purchasing a specific piece of equipment),

OR

- A Temporary Restriction of all or a specified amount of funds until issues or assurances have been resolved.
- Restricted funds may only be used <u>after a Revised</u> <u>Notice of Grant Award</u> is issued releasing the restriction.

Restrict funds until a Bank Account is established

ONLY BE LIFTED BY A REVISED NOTICE OF GRANT AWARD.

RESTRICTION: NO FUNDS MAY BE EXPENDED FOR THIS GRANT UNTIL THE GRANTEE INSTITUTION ESTABLISHES AN INTERNATIONAL BANK ACCOUNT IN CHINA.

Restriction: This award is issued with a Federal-wide Assurance of Protection (FWA00000294) for Human Subjects for the grantee institution that expired 04/19/04. The grantee institution must contact the Office for Human Research Protections (OHRP) within 50 days of the issue date of this award. Information on and instructions for submitting and negotiating a Federal-wide Assurance are available at the OHRP website http://ohrp.osophs.dhhs.gov/. The grantee institution must provide NIAID with the submission date of required Assurance documents to OHRP. The grantee is then responsible for notifying the NIAID when OHRP has approved the Assurance and for providing NIAID with a certification of IRB approval.

The grantee institution may conduct only activities that are clearly severable and independent from activities that involve human subjects until OHRP has approved an Assurance and the NIAID has received and accepted the grantee institution's certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects for any period not covered by both an OHRP approved Federal-wide Assurance and an IRB approval consistent with 45 CFR Part 46.

Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

Refer to the MIH Grants Policy Statement for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

Annual Financial Status Reports (Form SF-269) are required from foreign grantees. (NIH Guide, April 5, 1999). The Financial Status Report form is available at: http://grants.nih.gov/grants/forms.htm

This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address:

http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Grant Award. Restricted use of money for Human Subject until FWA approved

Addressed the need for Financial Status Reports

Referenced the NIAID rules on Human Subject Research

Programmatic Terms of Award

- Programmatic Terms of Award are a part of all Cooperative Agreements awards
- They are specific to the grant initiative and/or award.
- They are organized in the following sections:
 - Applicability
 - Awardee Rights and Responsibilities
 - NIAID Staff Responsibilities
 - Collaborative Responsibilities
 - Arbitration

Revised Notice of Grant Award

- Once an award is issued, it is sometimes revised to change the dollar amounts, or to lift a restriction on funds.
- The Revised NGA will always indicate:
 - The <u>AMOUNT</u> of the increase or decrease, or if there has been no dollar change.
 - A <u>TERM</u> indicating what action has been taken (e.g. Offset taken, Carryover applied, supplement funds given, restriction lifted and funds released, change in Budget period, etc.).

NIH Grants Policy Statement

- The NIH Grants Policy Statement (GPS) summarizes all policy requirements that serve as terms and conditions of NIH grant awards.
- The Grants Policy Statement is available on the web at:

http://grants2.nih.gov/grants/policy/ nihgps_2003/index.htm.

Consortiums

Consortium Partners

- Grantees must have written agreements for <u>EACH</u> Consortium Partner.
- o Each agreement should address the following:
 - Scientific work scope
 - Terms of Award
 - Administrative requirements
 - Report Requirements

NIH Grants Policy Statement

ctions Requiring NIH Prior Written Approval

- Change in scope, including significant re-budgeting
- Pre-award costs
- Changes in status, including absence, of PI and other key personnel
- Change in grantee organizational status
- Deviation from restrictions on Notice of Grant Award
- Carryover of unobligated balances
- Transfer of amounts from trainee costs
- Capital expenditures
- Need for additional NIH funds
- Combining the charges of closely related grants

NIH Grants Policy Statement

Change in Scope

- Actions likely to be considered a change in scope include:
 - Change in specific aims
 - Substitution of one animal model for another
 - Shifting of research emphasis from one disease to another
 - A clinical hold by the U.S. Food and Drug Administration (FDA) under a study involving an IND or an IDE
 - Applying a new technology
 - Transferring the performance of substantive programmatic work
 - Change in key personnel
 - Significant rebudgeting
 - Rebudgeting of funds into or out of the patient care line
- If you think an action may constitute a change in scope, please ask your program and/or Grants Management contact.

Terms and Conditions

Audit

Foreign grantees are subject to the audit requirements as set forth in <u>OMB</u>
 <u>Circular A-133</u>. A-133 requires that any recipient or sub-recipient that expends \$500,000 or more in a year in Federal awards shall have a single or programspecific audit conducted for that year.

Terms and Conditions

Reports and Records

- Foreign grantee institutions must submit reports in English and in terms of U.S. dollars.
- Record retention and audit requirements are the same as those for grants to domestic institutions.

Important Websites

NIAID, NIH, and Funding Opportunities Websites

NIH Websites

General

- National Institutes of Health http://www.nih.gov
- o Fogarty International Center <u>http://www.fic.nih.gov/</u>
- Notice of Grant Award
 http://grants.nih.gov/grants/policy/nihgps_2003/NIHG PS_Part5.htm#_Toc54600106/
- NIH Grants Policy Statement
 http://grants2.nih.gov/grants/policy/nihgps_2003/index.htm

NIAID Websites

- National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov/
- NIAID Funding Page <u>http://www.niaid.nih.gov/ncn/</u>
- NIAID International Grants and Contacts
 http://www.niaid.nih.gov/ncn/grants/int/default.htm
- Grant Application Basics
 http://www.niaid.nih.gov/ncn/grants/basics/index.htm

NIAID Websites

- Checklists for Applications <u>http://www.niaid.nih.gov/ncn/grants/charts/checklists.htm</u>
- NIAID Clinical Terms of Award <u>http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf</u>
- "All About Grants" Tutorials <u>http://www.niaid.nih.gov/ncn/grants</u>
- International Resources <u>http://www.niaid.nih.gov/ncn/grants/int/default.htm</u>

NIH Websites

- NIH Grants and Funding Opportunities http://grants1.nih.gov/grants/index.cfm
- NIH Guide to Grants and Contracts <u>http://grants1.nih.gov/grants/guide/index.html</u>
- NIH Extramural Programs <u>http://grants.nih.gov/grants/funding/funding.htm</u>
- NIH Grants Management- Foreign Grants <u>http://odoerdb2.od.nih.gov/gmac/topics/foreign</u> main.html

NIH Websites

- Office of Laboratory Animal Welfare (OLAW) http://grants.nih.gov/grants/olaw/olaw.htm
- Office of Human Research Protection (OHRP) http://ohrp.osophs.dhhs.gov/index.htm